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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,249	11/05/1999	JAY S. SCHNEIDER	SCH01.NP001	4962

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EXAMINER	
SCHMIDT, MARY M	
ART UNIT	**PAPER NUMBER**
1635	16

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/435,249	SCHNEIDER, JAY S.	
	Examiner	Art Unit	
	Mary Schmidt	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9-12 and 23-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4 and 9-12* is/are allowed.

6)☒ Claim(s) *23-29 and 31-33* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/02 has been entered.

Specification

2. The specification is objected to because the instant specification on pages 8 and 9 recites embedded hyperlinks and/or other forms of browser-executable code, that are impermissible and must be deleted. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 (p), paragraph I regarding incorporation by reference. Furthermore, if the application should issue and be placed on the Official web page, the URL may be interpreted as a valid HTML code and become a live web link, transferring a user to a commercial web site. Office policy does not permit the Office to link to any commercial site because the Office exercises no control over the organization, views or accuracy of the information contained on these outside sites.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-29 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating Parkinson's disease in mammals comprising administering SEQ ID Nos:1-5 for down regulation of GAD via the specific routes of administration claimed in instant claims 1 and 9, does not reasonably provide enablement for administration of any of antisense to GAD as instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

New claims 23-29 and 31-33 are rejected for the same reasons of record as set forth in the previous Official Actions on the merits mailed 03/30/00, 01/03/01 and 08/13/01 since they are drawn to any antisense to any GAD gene. Since there is a high level of unpredictability in the art for design of antisense to any particular gene target, especially for use in whole organisms as argued previously, one of skill in the art would necessarily practice undue experimentation to make and use any antisense to any GAD gene for the functions claimed. Although the specification taught administration of SEQ ID NOS:1-5, which were shown in the specification to function for downregulation of GAD65 or GAD67 in whole organisms having an art-recognized induced Parkinson disease state, this teaching does not correlate to the design and use

of any other individual antisense oligonucleotides in whole organisms for the therapeutic purposes claimed.

Therefore, while the specification is enabling for administration of the individual SEQ ID NOS. 1-5 to specific GAD gene targets, the specification as filed is not enabled for antisense to any GAD gene as claimed nor administration of the SEQ ID NOS:1-5 to any GAD gene as claimed.

Response to Arguments

5. Applicant's arguments filed 11/13/01 have been fully considered but they are not persuasive.

On pages 4-6 of the response filed 11/13/01, Applicant traverses the previous rejection of claims 1-22 under 35 U.S.C. 112, lack of enablement.

Applicants' wrote that "Any assertion by the Patent Office that an enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed.... The only reasoning provided in the Office Action is that 1) the claims are directed to any antisense or triplex oligonucleotide; and 2) the claims are directed to any route of administration. Applicants has amended claims 1-4 and 9-12 and has presented new claims 23-33, which are amply enabled by the specification."

Applicants' have overcome the rejection regarding the routes of administration of the antisense administered to the mammals by specifying the specific routes of administration, and

have overcome partially the rejection as to the breath of antisense claimed by specifying SEQ ID NOS:1-5.

Allowable Subject Matter

6. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 1-4 and 9-12 are allowable.

8. The claims 1-4, 9-12, and 23-33 are free of the prior art since the antisense oligonucleotide sequences of SEQ ID NO:1 were not taught in the art at the time the invention was made nor were methods of treatment of Parkinson's disease via administration of these antisense to the nigra pars reticulata via a cannula or internal globus pallidus via a cannula taught in the prior art prior to the instant invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3413.

SEAN McGARRY
PRIMARY EXAMINER
1635

M. M. Schmidt
June 3, 2002